No. 20-1758

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

JUNO THERAPEUTICS, INC., SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,

Plaintiffs-Appellees,

v.

KITE PHARMA, INC.,

Defendant-Appellant.

On Appeal from the United States District Court
for the Central District of California, No. 17-cv-07639,
Hon. Philip S. Gutierrez

BRIEF OF ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC., ALBERT EINSTEIN COLLEGE OF MEDICINE, AND THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER AS *AMICI CURIAE* IN SUPPORT OF REHEARING OR REHEARING EN BANC

Jesse Snyder
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
jsnyder@kslaw.com

I. Cason Hewgley IV
KING & SPALDING LLP
1100 Louisiana Street
Suite 4100
Houston, TX 77002
(713) 751-3200
chewgley@kslaw.com

Vanessa Yen
Counsel of Record
Evan Diamond
KING & SPALDING LLP
1185 Avenue of the Americas
34th Floor
New York, NY 10036
(212) 556-2100
vyen@kslaw.com
ediamond@kslaw.com

Counsel for Amici Curiae

November 10, 2021

CERTIFICATE OF INTEREST

Counsel for *amici curiae* certifies the following:

1. The full name of every amicus represented by me:

St. Jude Children's Research Hospital, Inc.
Albert Einstein College of Medicine
The University of Texas MD Anderson Cancer Center

2. The name of the real party in interest represented by me:

St. Jude Children's Research Hospital, Inc.
Albert Einstein College of Medicine
The University of Texas MD Anderson Cancer Center

3. Parent corporations and publicly held companies that own 10% or more of stock in the party:

None.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

None.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary):

None.

6. The organizational victims and bankruptcy cases applicable to this appeal:

None.

Dated: November 10, 2021

/s/ Jesse Snyder
Jesse Snyder

Counsel for Amici Curiae

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STATEMENT OF INTEREST

Amici have an institutionally vested interest in the outcome of this case, and they offer perspectives that will assist this Court. **St. Jude Children's Research Hospital, Inc.** is the only National Cancer Institute-designated Comprehensive Cancer Center devoted solely to children. For more than 60 years, **Albert Einstein College of Medicine's** diverse faculty and staff have set the standard for excellence in medical and graduate education and patient-centered clinical care, and it has made major contributions to scientific research enhancing human health. **The University of Texas MD Anderson Cancer Center** ranks as one of the world's most respected centers focused on cancer patient care, research, education, and prevention.

Amici are familiar with the patent-in-suit, and the significant benefits that this patent's science provides to further research and to treat cancer. *Amici* are likewise conversant in researching, developing, and bringing to bear new and innovative therapies for fighting cancer, including technologies that are the subject of existing patent protection and pending patent applications. Because the patent-in-suit represents groundbreaking technology in the treatment of cancer, and because it

stands as an exemplar of what patent protection can provide to institutions dedicated to cutting-edge research to eradicate the real-world toll levied by cancer, *Amici* offer important perspectives not available from any party.

STATEMENT OF COMPLIANCE WITH RULE 29(a)

This brief is submitted in accordance with Rule 29(a) of the Federal Rules of Appellate Procedure. All parties have consented to this filing. *See also* Fed. Cir. R. 29(c). To secure Kite's consent, *Amici* note that King & Spalding represented non-party Bristol Myers Squibb Company ("BMS") in connection with a third-party subpoena issued to BMS in the underlying district court proceedings.

No party or party's counsel authored this brief in whole or in part; no party or party's counsel contributed money to fund the preparation or submission of this brief; and no other person except *Amici curiae*, its members, or its counsel contributed money intended to fund the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

INTRODUCTION

This is a rare instance where *en banc* determination is needed. *See* Fed. R. App. P. 35(a); *Franklin-Mason v. United States*, 692 F. App'x 633, 634 (Fed. Cir. 2017) (explaining the standard). *Amici* rarely file similar amicus briefs in patent-related cases like this one, and they only do so now to underscore the threat this case poses to academic research.

The Panel catches *Amici* in an impossible bind for their ongoing and future innovation efforts with chimeric antigen receptors ("CARs") and other lifesaving biotechnologies. Either (1) *Amici* pursue exceedingly narrow, ineffective patent protection readily evaded by copycats using routine, preexisting technology—thereby disincentivizing further investment towards developing treatments for patients; or (2) *Amici* and their researchers expend their limited resources and time attempting to satisfy the Panel's super-heightened description standard by exhaustively identifying, making, and testing innumerable embodiments of old technology, rather than devoting resources and time towards new, innovative technologies and improvements. Neither is tenable, and both will harm innovation without any corresponding benefit to the public.

ARGUMENT

I. The Panel's Heightened Written Description Requirement Discriminates Against Biotechnology Innovations.

Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*) held that 35 U.S.C. § 112, ¶ 1 contains a "written description requirement," which need only (1) "allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed," and (2) "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date," *id.* at 1351.

Amici are deeply concerned that the Panel's decision morphs the written description requirement into an unattainable standard—aimed (perhaps exclusively) at cutting-edge innovations in the biotechnology and pharmaceutical fields—that significantly threatens the lifesaving efforts of *Amici* and their research collaborators.

According to the Panel, a claim reciting a groundbreaking biotechnology innovation (here, an intracellular domain for CARs), and further generically reciting the well-established, readily-made targeting domain of a CAR (particularly including an "scFv" binding molecule), could never satisfy the written description requirement—unless the

specification describes ***all "known and unknown" embodiments*** of the prior-art technology element. *See* Op. at 11.[1] Even for the dependent claims to a specific binding target ("CD19"), the Panel engrafts a prerequisite of making and of testing "***millions of billions***" of potential CD19-binding scFvs before an adequate written description can be realized. *See id.* at 15–18. The Panel thus deprives inventors of effective patent protection, unless (or even if) they exhaustively make and describe innumerable embodiments for a generic, prior-art element.

That has never been the law. Rather, "an applicant is ***not required to describe*** in the specification ***every conceivable and possible future embodiment*** of his invention." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003). Requiring disclosure of every possible embodiment would "impose an ***impossible burden*** on inventors and thus on the patent system." *See In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977). "There cannot, in an effective patent system, be such a burden placed on the right to broad claims." *Id.*

[1] Unless otherwise noted, all emphasis is added, and all internal citations and internal quotation marks are omitted.

The Panel decision directly conflicts with this Court's predecessor. *See In re Herschler*, 591 F.2d 693, 700–01 (C.C.P.A. 1979); *see also Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 928 (Fed. Cir. 2004) (discussing *Herschler*). *Herschler* held that method claims reciting dimethylsulfoxide ("DMSO") as a skin penetration enhancer for a generic "physiologically active steroidal agent" were ***not*** invalid for lack of written description—even though the specification exemplified only a ***single*** "steroidal agent"—because (1) an artisan knew of additional "steroidal agents," and understood DMSO would perform similarly for steroids generally; and because (2) the invention was "steroids ... as a class of compounds carried through a layer of skin by DMSO," ***not*** "novel 'steroidal agents.'" *See Herschler*, 591 F.2d at 700–01; *see also Rochester*, 358 F.3d at 928 ("The ***novelty*** in [*Herschler*'s] invention was the DMSO solvent, ***not the steroids***."). *Herschler* did ***not*** require the description or "possession" of every ***known and unknown*** "physiologically active steroidal agent," or that the inventors had made and tested innumerable putative "steroidal agents" for potential "physiological activity"—recognizing the inventors did not seek to monopolize "novel steroidal agents" *per se*. *See id.*

Herschler controls and dictates a finding of adequate written description here: (1) skilled artisans knew of exemplary binding elements such as scFvs in the art, and understood that the innovative claimed CAR backbone would perform similarly with scFvs generally, and (2) the ***novelty*** of the claimed invention was in the new and improved CAR intracellular domain, ***not the binding element or scFv used as such***. The inventors undisputedly "possessed" as well as described and enabled their actual claimed innovation—a novel CAR design with substantially improved properties—and they did not seek to monopolize all "novel scFvs" *per se*.

In flipping the written description requirement on its head, the Panel neglects that "the patent specification is ***written for a person of skill in the art***, and ***such a person comes to the patent with the knowledge of what has come before***." *See Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1167 (Fed. Cir. 2012); *see also Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1346 (Fed. Cir. 2000) ("It cannot be forgotten that the disclosure is not addressed to the public generally, but to those skilled in the art."). For cutting-edge biotechnology fields, like the design of novel CAR therapeutics at hand,

the "ordinary" artisan can be highly skilled vis-à-vis the general public; and what may seem prohibitively complex and unpredictable to those outside the field will in many instances be well-established, routine, and predictable to those of ordinary skill within it.[2]

It is thus critical that this Court avoid the mistake underlying the Panel's super-heightened description requirement: that the biotechnology and pharmaceutical fields are categorically "unpredictable arts," always requiring a higher level of disclosure than so-called "predictable arts." *Cf. Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1361 (Fed. Cir. 2018) (distinguishing the "level of detail required" for "unpredictable arts" versus "predictable arts"). Instead, each assessment of the description for a biotechnology or pharmaceutical patent should be specific to the "particular case" and "aspect at issue," and it must account and adjust for "the state of the science" and "the state of relevant knowledge" attributed to the artisan—including "the

[2] Trial testimony described the ordinary artisan as "an M.D. or a[] Ph.D. in immunology, biochemistry, cell biology, molecular biology or related discipline, and at least two years of experience in conducting laboratory research on chimeric TCR therapies, TCRs, T-cells or other types of immune cells"—armed with "knowledge of T-cell biology and knowledge of and skills related to molecular biology techniques useful in immunology research." Appx33632.

scientific and technologic knowledge already in existence," "the maturity of the science or technology," and the evolving "balance ... between what is known [to ordinary artisans] and what is added by each inventive contribution." *See Capon v. Eshhar*, 418 F.3d 1349, 1357–59 (Fed. Cir. 2005). Especially where a jury received substantial testimony and evidence on these issues, and it finds that written description has not been proven inadequate by clear and convincing evidence, such a factual finding should not be second-guessed lightly. *See, e.g.*, *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1039 (Fed. Cir. 2016) (*en banc*) ("[T]he appellate function … requir[es] appropriate deference be applied to the review of fact findings.").

There is no reason biotechnology innovators writ large, but not those in "predictable" fields, should be held to the Panel's impossible standard. When finding adequate support for a claim generically reciting "local color displays," the Court did ***not*** require the inventors to describe every "color display" embodiment ***known and unknown*** as of their 1985 filing—but rather was satisfied with a specification mentioning "cathode ray tubes ... or other display transducers" along with the statement that "the present invention can be applied to a wide variety of display and

vision aid devices." *See Honeywell Int'l, Inc. v. U.S.*, 609 F.3d 1292, 1301 (Fed. Cir. 2010). When the Court found adequate support for claims reciting a generic "light guide," the Court did ***not*** insist on the disclosure of all ***known and unknown*** "light guides"—satisfied that the specification disclosed one "type of light guide," and that "various types of light guides were well-known in the art." *See Hologic*, 884 F.3d at 1361–62.

These cases illustrate the unfairness that the Panel decision levies on biotechnology and pharmaceutical innovators. For it is implausible that *Honeywell*'s inventors, in their 1985 application, should have been required to describe every "color display" technology available in 2021, including those that were "unknown" and "unpredictable" (and perhaps inconceivable) to the inventors as of their filing. Such a policy against claim elements generically reciting established technology, whether applied to the mechanical arts, the electrical arts, the biotechnology and pharmaceutical arts, or otherwise, would be "both shortsighted and unsound from the standpoint of promoting progress in the useful arts"—"the constitutional purpose of the patent laws"—and would undermine "an effective patent system." *See Hogan*, 559 F.2d at 606.

II. The Decision Stymies Innovative, Lifesaving Technologies.

The Panel's new written description standard forces *Amici* to (1) obtain only exceedingly narrow, ineffective patent protection for groundbreaking inventions, or (2) divert their limited resources towards making innumerable embodiments of old technologies—in either case, damaging the efforts of *Amici* and their research collaborators to discover and develop cutting-edge, innovative technologies for the treatment of cancer and other life-threatening conditions.

The CAR technology before the Panel exemplifies why "narrow claiming" of elements reflecting well-established technology is an illusory option. If the inventors had described the full sequence of all "four or five" CD19-binding scFvs extant as of their filing, and had limited the scFv element of their claimed CAR constructs solely to those embodiments, then any infringer could potentially "design-around" the claims—using the routine, well-established prior art scFv technology to generate a new CD19-binding scFv. *See, e.g.*, *Enzo Biochem, Inc. v. Gen-Probe*, 323 F.3d 956, 966 (Fed. Cir. 2002) (describing a biotechnology innovator's concern that, without "broad claim scope," "copyists" making

a "minor change" could "avoid infringement" while "still exploiting the benefits of [the] invention").

Nor can *Amici* realistically satisfy the Panel's super-heightened requirement for adequately supporting generic prior-art elements in biotechnology claims. Under the Panel's reasoning, a patent application would have to describe (as well as make and test) countless "***known and unknown***" permutations of an element—even if those variations have nothing to do with the novelty of the claims. As non-profit, academic research institutions, *Amici* would be substantially drained of financial resources if they were to undertake such an exhaustive (but scientifically insignificant) effort. Even if *Amici* had the resources, the potentially endless work required to make and test "millions of billions" of biomolecules or compounds (*see* Op. at 15, 17–18) would be a huge, counterproductive distraction from the missions of *Amici* and similarly-situated institutions to support innovative research toward treating cancer and other serious diseases.

This Court has recognized how an unduly burdensome disclosure requirement can harm *Amici*, their researchers, innovation generally, and the public good:

> Requiring inclusion in the patent of known scientific/technological information would add an imprecise and open-ended criterion to the content of patent specifications, could greatly enlarge the content of patent specifications and unnecessarily increase the cost of preparing and prosecuting patent applications, and could tend to obfuscate rather than highlight the contribution to which the patent is directed.

Ajinomoto, 228 F.3d at 1346–47. That burden also redounds to patent examiners. Accordingly, "a patent ***need not teach***, and preferably omits, what is ***well known in the art***." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

The Panel decision thus puts research institutions like *Amici* in an intractable dilemma. They can claim narrowly even as to well-known prior art components of their inventions—resulting in weak, readily designed-around patents that would probably fail to attract the investment needed to bring innovative technologies to market for the benefit of patients. Or, they can attempt to spend unfathomable time and resources to satisfy the Panel's new written description requirement. Or, they can abandon patenting entirely—while knowing that a "publish and hope" approach to academic research is rarely enough to spur further development and bring groundbreaking therapies to market for patients. *See* Swearingen & Slaper, *Economic Impacts of Technology Transfer: Two*

Case Studies From the U.S. Department of Defense, Tech. Transfer (June 2012), https://tinyurl.com/3d6hebmy; Stevens, et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, N. Engl. J. Med. (Feb. 10, 2011), https://tinyurl.com/6bmkesxk.

These results cannot be squared with the text and purpose of 35 U.S.C. § 112, especially when "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002).

CONCLUSION

This Court should grant the petition and rehear the appeal.

Respectfully submitted,

/s/ Jesse Snyder

Jesse Snyder
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
jsnyder@kslaw.com

I. Cason Hewgley IV
KING & SPALDING LLP
1100 Louisiana Street
Suite 4100
Houston, TX 77002
(713) 751-3200
chewgley@kslaw.com

Vanessa Yen
Counsel of Record
Evan Diamond
KING & SPALDING LLP
1185 Avenue of the Americas
34th Floor
New York, NY 10036
(212) 556-2100
vyen@kslaw.com
ediamond@kslaw.com

Counsel for Amici Curiae

November 10, 2021

CERTIFICATE OF COMPLIANCE

In accordance with Federal Rule of Appellate Procedure 32(g), the undersigned counsel for *Amici* certifies that this brief complies with this Court's published filing requirements:

The brief complies with the type-volume limitation of Federal Circuit Rule 35(6)(3) because it contains less than 2,523 words, including footnotes and excluding the parts of the brief exempted by Federal Circuit Rule 32(b)(2) and Federal Rule of Appellate Procedure 32(f); and

And the brief complies with the typeface and style requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6) because this document has been prepared using Microsoft Office Word 365 ProPlus and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: November 10, 2021

/s/ Jesse Snyder
Jesse Snyder
Counsel for Amici Curiae